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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/373,352 | 08/12/1999 | DAVID EMIL EDGREN | ARC2247R1 | 2512 |

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ALZA CORPORATION
1900 CHARLESTON ROAD
P.O. BOX 7210
MOUNTAIN VIEW, CA 94039-7210

EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/373,352

Applicant(s)

EDGREN ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/15/2002, 4/14/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-50 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claims omit one or more of the following elements: The Specification appears to indicate that a interior membrane formed around the core comprising a polymer possessing a lipophilic-attracting property and exterior membrane form around the interior membrane comprising a polymer permeable to the passage of an aqueous fluid and a plasticizer are essential (Specification, Pg. 6-12). As such, said elements should be in all of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 20, 37-44, 46,48,49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzi et al. (US Pat. 5,629,017) in view of Benton et al. (US Pat. 4,876,094) and Oshlack et al. (US Pat. 5,356,467) for the reasons of record set forth in the prior Office Actions, including the Advisory Action (8/22/2002), in further view of Cortese et al. (US Pat. 4,327,725) and the further reasons below.

Pozzi et al. teaches a dosage form comprising a core containing drug coated by a hydrophobic layer containing fats or waxes, such as carnauba wax, beeswax, hydrogenated castor oil, petroleum wax and mixtures of mono-,di- and tri-glycerides of polyethylene glycol, and a water-soluble film forming material, such as hydroxyalkyl-celluloses, in an amount of about between 5 and 30% of the hydrophobic material and a surfactant, such as ethoxylated fatty alcohols, in an amount of about 5 to 20% of the hydrophobic material (Columns 3, 4). It is taught that the hydrophobic layer can be coated by a polymeric enteric coating such as cellulose acetate phthalate, methacrylic acid-methacrylic acid ester copolymers, HPMC phthalate, polyvinyl acetate phthalate, hydroxyethylcellulose phthalate and cellulose acetate tetraphthalate to which a plasticizer can be added (Column 6, lines 52-68).

Benton teaches dual coated dosage forms comprising a core containing a drug, a hydrophobic layer containing fats and a second layer contain zein to which a plasticizer can be added (Columns 3, 4). It is taught that the second coat enables the dosage form to be solubilize only in a limited pH range found in the GI tract. (Column 51-56).

Oshlack et al. (US Pat. 5,356,467) teaches that the release properties of zein containing coatings can be further adjusted to a desired rate by use of hydrophilic polymers (Column 8,

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lines 53-68). It is taught that the controlled release coating can include an exit means comprising at least one passageway (Column 9, lines 66-68, Column 10, lines 1-12).

Cortese et al. teach the use of a fluid swellable hydrogel in the core which acts to drive the active agent through a passage way in the device (See entire reference).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a dosage form containing a core, lipophilic layer and hydrophilic layer containing a peptide having an expandable composition in the core. However, the prior art amply suggests the same as dosage forms containing lipophilic and hydrophilic layers and coating membranes containing zein and expandable compositions are known in the art. As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art as above with the expectation of obtaining a dosage form which can be formulated to deliver drug in the GI tract and drive the active agent out of the dosage form as desired.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons set forth in the Advisory Action (8/22/2002).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 19, 20, 37-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeitoun et al. (U.S. Pat. 4,432,966) over Seminoff et al. (U.S. Pat. 5,126,146), Staniforth (US Pat. 5,504,614) and Oshlack et al. (US Pat. 5,356,467) for the reasons set forth in the prior Office Actions, including the Advisory Action (8/22/2002), and the further reasons below..

Zeitoun et al. teach a dosage form containing a core containing a drug coated with a first layer containing ethyl cellulose which is covered by an enteric coating such as cellulose acetylphthalate, hydroxypropylmethylcellulose phthalate, keratin, and plasticizers (Columns 1,2).

Seminoff et al. teach that flux regulators and surfactants can be added ethyl cellulose coatings to achieve the desired permeability and improve blending and dispersion of the polymer, respectively (Columns 3, 4).

Staniforth teaches that the rate of release can be modified by making an orifice in the coated device and the use of swelling agents (Column 9)

Oshlack et al. is cited here for the same reasons as above and incorporated herein to avoid repetition.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a dosage form containing a core, lipophilic layer and hydrophilic layer containing a peptide. However, the prior art amply suggests the same as dosage forms containing lipophilic and hydrophilic layers and coating membranes containing zein are known in the art. As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art as above with the expectation of obtaining a dosage form which can be formulated to deliver drug in the GI tract as desired and that the swelling agents will facilitate entry of environmental fluids.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons set forth in the Advisory Action (8/22/2002).

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

6/30/2003



JOHN PAK
PRIMARY EXAMINER
GROUP 1600